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September 11, 2024

Via ECF

Hon. Gregory H. Woods
United States District Judge
Southern District of New York
United States Courthouse
500 Pearl St., Room 2260
New York, New York 10007

Re: *City of New York v. EnviroMD Group, LLC*, et al
Civ Action No: 24-cv-05161 (GHW) (JW)

Dear Judge Woods:

This letter is respectfully submitted on behalf of Defendant Kayla Wholesale, Inc., d/b/a The Vapery (“Kayla”) pursuant to Your Honor’s Individual Rule 2 E to respectfully request a pre motion conference for purposes of moving under FRCP 12 (b) (6) to dismiss the Second Amended Complaint against Kayla. As the Court is aware, this action was removed to this Court from the Supreme Court, State of New York, County of New York [Index no. 451009/2024] and after amendments to the Complaint, includes causes of action under the Family Smoking Prevention and Tobacco Control Act (21 USC 387 et seq.) (the “Tobacco Control Act”), the Prevent All Cigarettes Trafficking Act (“PACT Act”) (15 USC 375 et seq), the New York State Public Health Law, the New York City Administrative Code, and a claim for Public Nuisance. This matter involves the alleged sale of electronic cigarettes/electronic nicotine delivery systems (“ENDS” products) by a group of defendants, against whom allegations have been strung together in a prejudicial and conclusory manner, even after two amendments to the Complaint. "In order to survive a motion to dismiss under Rule 12(b)(6), a complaint must allege a plausible set of facts sufficient `to raise a right to relief above the speculative level.'" *Operating Local 649 Annuity Trust Fund v. Smith Barney Fund Mgmt LLC*, 595 F.3d 86, 91 (2d Cir. 2010) (quoting *Bell Atl.Corp. v. Twombly*, 550 US 544 (2007)).

The Complaint improperly and confusingly alleges, among other things, that *all defendants* have violated *every* federal, state and city law related to the sales at issue [Complaint, ¶1 1]. To the extent that more specific allegations against Kayla can be parsed, the allegations should be dismissed as more fully set forth herein. Kayla joins in, and incorporates by reference, the defenses asserted by each of the co-defendants in this matter (including but not limited to standing defenses relating to the PACT Act and other statutes) to the above alleged statutory violations and to the public nuisance allegations, to every extent that these defenses are applicable to Kayla. See e-filed Document no. 65 dated September 11, 2024.

Kayla is accused of selling product to a distributor known as Star Vape between August and November of 2020. Any PACT Act allegations from this (or any prior) time period must be

dismissed because they pre-dated applicable statutes and regulations.¹ As examples, the Consolidated Appropriations Act of 2022 (“CAA”) amended the definition of “tobacco product” to include those that contain nicotine from any source, effective April 14, 2022. [21 USC § 321(rr)] The FDA’s own regulations pursuant to the CAA were not effective until March 20, 2023. Certain registration requirements only became effective March 27, 2021. The federal definition of cigarettes was amended to include ENDS products on March 27, 2021.² To the extent that Kayla is accused of violations pertaining to mailing and delivery of product, US postal regulations/final rules banning the mailing of ENDS products through the US postal system did not become effective until October 21, 2021 [86 Fed. Register 201, sec 471.5, 472.1].³ Finally, New York State’s prohibition on sales of flavored e-cigarettes became effective on May 18, 2020, and New York City’s ban became effective on July 1, 2020. Any Complaint allegations that precede these dates must be dismissed.

The Complaint also generally alleges sales in violation of the FDA’s premarket authorization requirements pursuant to 21 USC § 387j(a)(1), (2). But the FDA’s premarket authorization procedures were ruled to be arbitrary and capricious in *Wages and White Lion Investments LLC v. Food and Drug Administration*, 90 F. 4th 357 (5th Cir. 2024). The US Supreme Court will be reviewing these issues in the upcoming term [Docket no. 23-1038, July 2, 2024]. The FDA itself has rescinded marketing denial orders issued to JUUL Labs.⁴ Since FDA approval of these products (or the denial of same) lies at the heart of this matter, this matter should, at the very least, be held in abeyance (if it is not dismissed outright) until the Supreme Court rules on this issue.

This action is contrary to enforcement schemes for the various statutes. There is no allegation that any warning letters were sent to Kayla, contrary to the FDA’s usual enforcement procedures, as referenced in the Complaint. The relevant sections of the New York Public Health Law indicate that enforcement is through hearings conducted by an enforcement officer. [PHL 1399-aa(1), 1399-ee(1)]. In addition, enforcement of New York City Administrative Code provisions is administrative, and a proceeding to recover civil penalties requires a Notice of Violation to the NYC Office of Administrative Tribunals, absent in this matter. [NYC Administrative Code § 17-717]. Furthermore, 24 RCNY 28-02(a) provides that tobacco wholesalers may sell or offer for sale flavored e-cigarettes and flavored e-liquids where the sale is made to a tobacco bar. Here, adding to the fatal vagueness of this Complaint, and with very limited exceptions, this pleading does not identify to whom sales were made or offered. Instead,

¹ The only other alleged sales were two occasions of sales in 2024 of a small quantity of product to an individual later revealed to have been a City Investigator. The City has conceded that Kayla’s website was shortly thereafter shut down, thus rendering moot any request for an injunction.

² This Amendment was pursuant to the 2021 Omnibus Appropriations Bill which amended the PACT Act.

³ Any accusation that Kayla violated PHL provisions regarding marking of packages containing vapor products may be pre-empted by 15 USC 376a(e)(5)(A)(iv), which provides in relevant part, that no state or local government may enact or enforce any law relating to delivery sales that restrict deliveries of cigarettes or smokeless tobacco to consumers by common carriers or other delivery services by requiring that packages contain any particular labels, notice, or markings.

⁴ “Update on FDA’s Scientific Review of JUUL Product Applications” June 6, 2024.

the Complaint is rife with vague and unsustainable allegations such as those relating to a purported “internet tracking service” which cannot withstand dismissal.⁵

Any Public Nuisance allegation against Kayla involving alleged marketing of product to minors must be dismissed because Kayla is not accused of any such sales. Allegations regarding hazardous waste or other public nuisance are alleged in a conclusory manner that cannot withstand dismissal. Conduct constituting a public nuisance must amount to a substantial interference with the exercise of a common right of the public, endangering property, health, safety or comfort of a considerable number of persons. *In re Methyl Butyl Ether Prods Liab. Litig.* 725 F.3d 65, 121 (2d Cir. 2013). Defendant’s conduct or omissions must have created, contributed to, or maintained a public nuisance. *Hicksville Water Dist. v. Phillips Elec. North Am. Corp.*, No. 17-CF-4442 (ADS) (ARL), 2018 U.S. Dist. LEXIS 53342, at *19 (E.D.N.Y. March 29, 2018). See also, *Town of Islip v. Datre*, 245 F. Supp3d 397, 428 (EDNY 2017). Here, the City has not attributed the alleged “growing hazardous waste problem” to any actions or inactions of Kayla whether intentional or negligent, it has absurdly singled out e-cigarette use and disposal of lithium ion batteries, widely used in any number of unrelated electronic devices, and it has not specified any manner in which these products have endangered the health or safety of anyone, let alone a large number of persons in New York City, due to Kayla’s alleged actions. This allegation should be dismissed.

This action seeks penalties under the PHL and NYC Administrative Code, and the establishment of a “fund” to abate the alleged public nuisance. The overwhelming bulk of allegations against Kayla arise from alleged sales over a four month period in 2020. Thus, the public nuisance allegations should be dismissed pursuant to the three-year statute of limitations for such claims. *Sova v. Glasier*, 192 AD2d 1069 (4th Dept 1993). The PHL and New York City Administrative Code allegations should be dismissed pursuant to CPLR 214 (2), providing for a three-year limitations period. In addition, in the event the Court dismisses the federal claims, it should decline to exercise its supplemental jurisdiction over the state law claims.

For the foregoing reasons, Kayla requests a pre motion conference for the purpose of moving to dismiss the Second Amended Complaint.

Respectfully submitted,

Jeffrey Benjamin

Jeffrey Benjamin, Esq.

⁵ Allegations that unknown persons may have clicked on a website do not support violations especially when an internet search using the word “Kayla” produces dozens or hundreds of results including but not limited to a seller of Italian ices, photographers, an e-bay store, and various individuals.